

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Rittershaus and Thomas

Serial No.: (not yet assigned)

ART UNIT: (not yet assigned)

Filed: (concurrently herewith)

EXAMINER: (not yet assigned)

Entitled: MODULATION OF CHOLESTERYL
ESTER TRANSFER PROTEIN (CETP)
ACTIVITY

Divisional of U.S. Serial No. 08/945,289

Attorney Docket No.: TCS-411.1P US-1

Box Patent Application

Assistant Commissioner for Patents

Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

This paper is filed concurrently with the application papers requesting the filing of a divisional application based on U.S. Serial No. 08/945,289, filed October 17, 1997. Please enter the following amendments prior to calculation of the filing fee and prior to examination on the merits.

IN THE SPECIFICATION

Please delete the first paragraph of the specification regarding cross reference to related applications at page 1, lines 4-5, and substitute therefor:

--This is a divisional application of U.S. Serial No. 08/945,289, filed October 17, 1997, which is the United States national stage under 35 U.S.C. § 371 of international application No. PCT/US96/06147, filed May 1, 1996, which is a continuation-in-part application of U.S. Serial No. 08/432,483, filed May 1, 1995.--

Please replace the Sequence Listing at pp. 39-59 of the specification with the enclosed amended Sequence Listing and renumber the pages of the specification accordingly.

IN THE CLAIMS

Please cancel original Claims 1-27 and 30-36.

Please add new Claims 37, 38, and 39, as indicated below in clean form pursuant to 37 C.F.R. § 1.121(c)(1)(i). A marked up version of the new claims is attached pursuant to 37 C.F.R. § 1.121(c)(1)(ii) (Tab A), and a complete set of claims 28, 29, and 37-39 of this divisional application is attached pursuant to 37 C.F.R. § 1.121(c)(3) (Tab B).

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Newly Added Claims in Clean Form Pursuant to 37 C.F.R. § 1.121(c)(1)(i)

37. (new) The method according to claim 28, wherein the B cell epitope portion of the vaccine peptide comprises a carboxyl terminal region of human CETP consisting of between 6 and 26 consecutive amino acids of SEQ ID NO:1.

38. (new) The method according to claim 37, wherein the vaccine peptide comprises the amino acid sequence of SEQ ID NO:2.

39. (new) The method according to claim 37, wherein the vaccine peptide comprises a dimer of the amino acid sequence of SEQ ID NO:2.

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REMARKS

This application is a divisional of U.S. Serial No. 08/945,289, filed October 17, 1997. This divisional application is filed to receive consideration of additional embodiments of Applicants' invention disclosed in the specification as originally filed. In particular, claims 28 and 29, which were previously divided out of U.S. Serial No. 08/945,289, are presented for examination in this divisional application. As indicated above, Applicants have also added new claims 37-39, which depend from claim 28 and which are directed to particularly preferred embodiments of the invention.

The first paragraph of the specification has been amended to provide updated information regarding cross-references to related applications under 37 C.F.R. § 1.78. Entry of the amendment is respectfully requested.

Applicants have cancelled claims 1-27 and 30-36.

Applicants have added new claim 37, which is directed to a preferred embodiment of the method for therapeutically or prophylactically treating atherosclerosis according to claim 28, wherein the B cell epitope portion of the vaccine peptide used in the method comprises a carboxyl terminal region of human CETP consisting of between 6 and 26 consecutive amino acids of SEQ ID NO:1. Support for new claim 37 is found in original claim 13 and in the specification (see, e.g., p. 14, lines 5-10 of the specification). Accordingly, new claim 37 adds no new matter.

New claim 38 is directed to the particular embodiment of the method according to claim 37 wherein the vaccine peptide comprises the amino acid sequence of SEQ ID NO:2. Support for new claim 37 is found in original claim 8 and in the specification (see, e.g., Examples 1-10, pp. 27-38 of the specification; especially Example 10 and Figure 13, which show significantly lower percentage of atherosclerotic lesions developed in aortas of rabbits, which were fed an atherogenic diet and received a vaccine peptide comprising an amino acid sequence of SEQ ID NO:2)). Accordingly, new claim 38 adds no new matter.

New claim 39 is directed to the particular embodiment of the method according to claim 37 wherein the vaccine peptide specifically comprises a dimer of the amino acid sequence of

SEQ ID NO:2. Support for new claim 39 is found in the specification (see, e.g., p. 21, lines 17-21 of the specification). Accordingly, new claim 39 adds no new matter.

Entry of new claims 37, 38, and 39 is respectfully requested.

Applicants have replaced the original Sequence Listing at pp. 39-59 of the specification with the enclosed substitute sheets of an amended Sequence Listing. The enclosed amended Sequence Listing has been reformatted consistent with the latest rules for a Sequence Listing and to correct the attorney docket number. A substitute Computer Readable Form is also enclosed pursuant to 37 C.F.R. § 1.825(b).

Pursuant to 37 C.F.R. § 1.825(a), Applicants' undersigned attorney hereby states that sequence information of the amended Sequence Listing is the same as the sequence information in the original Sequence Listing and contains no new sequence information. The undersigned attorney further states that the substitute Computer Readable Form, submitted herewith in accordance with 37 C.F.R. § 1.825(b), is the same as the amended Sequence Listing.

Entry of the replacement Sequence Listing and substitute Computer Readable Form is respectfully requested.

Entry of all of the above amendments and examination of claims 28, 29, 37, 38, and 39 of this divisional application are respectfully solicited.

Respectfully submitted,



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CERTIFICATE OF MAILING BY "EXPRESS MAIL"

The undersigned hereby certifies that this correspondence listed above is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service under 37 CFR § 1.10, postage prepaid, Express Mailing Label No. **EL164335375US**, in an envelope addressed to the Asst. Commissioner for Patents, Box Patent Application, Washington, D.C. 20231 on the date indicated below.

August 30, 2001
Date

Stephanie L. Leicht
Stephanie L. Leicht

Marked Up Version of Amended Claims Pursuant to 37 C.F.R. § 1.121(c)(1)(ii)

37. (new) The method according to claim 28, wherein the B cell epitope portion of the vaccine peptide comprises a carboxyl terminal region of human CETP consisting of between 6 and 26 consecutive amino acids of SEQ ID NO:1.

38. (new) The method according to claim 37, wherein the vaccine peptide comprises the amino acid sequence of SEQ ID NO:2.

39. (new) The method according to claim 37, wherein the vaccine peptide comprises a dimer of the amino acid sequence of SEQ ID NO:2.

Accepted for filing

Complete Set of Claims Pursuant to 37 C.F.R. § 1.121(c)(3)

28. A method for therapeutically or prophylactically treating atherosclerosis in a human or other animal in need of treatment thereof comprising administering to said human or other animal a vaccine peptide in a pharmaceutically acceptable buffer, said vaccine peptide comprising a helper T cell epitope portion comprising a helper T cell epitope and B cell epitope portion comprising a B cell epitope of CETP.

29. The method for treating atherosclerosis according to claim 28 wherein said helper T cell epitope portion comprises a helper T cell epitope derived from an antigenic peptide selected from the group consisting of tetanus toxoid, diphtheria toxoid, pertussis vaccine, Bacille Calmette-Guerin (BCG), polio vaccine, measles vaccine, mumps vaccine, rubella vaccine, purified protein derivative of tuberculin, keyhole limpet hemocyanin, hsp70, and combinations thereof.

37. The method according to claim 28, wherein the B cell epitope portion of the vaccine peptide comprises a carboxyl terminal region of human CETP consisting of between 6 and 26 consecutive amino acids of SEQ ID NO:1.

38. The method according to claim 37, wherein the vaccine peptide comprises the amino acid sequence of SEQ ID NO:2.

39. The method according to claim 37, wherein the vaccine peptide comprises a dimer of the amino acid sequence of SEQ ID NO:2.